Delivering Efficiency on The Packing Line

Equipment suppliers can play a key role in ensuring pharmaceutical manufacturers can take a Right First Time approach to their packing requirements, says Richard Aitchison of ATS Packaging Machinery.

To the lay person, the pharmaceutical industry may appear to be bullet-proof, a sector that can survive and prosper whatever the economic climate. Just as the fact that we still have to eat, even in more straitened times, benefits food manufacturers, illness takes no notice of current market conditions. This means that, whether we are seeking treatment for a common cold or a more serious ailment, the pharmaceutical industry will always be needed to provide the remedy.

Even the unprecedented situation of the Covid-19 pandemic has brought about opportunities for the sector. In the USA, for example, a survey undertaken last year by The Harris Poll on behalf of Samueli Integrative Health Programs found that many adults planned to be more mindful of their self-care habits, with 80% of respondents saying that they would be more likely to practise regular self-care once the pandemic is over.

Sales of vitamins and minerals have also seen huge increases as consumers seek to boost their health and immunity. According to market researcher Kantar, UK sales reached record levels in 2020, with more than half the population having bought a supplement of some type in the past year.

That the pharmaceutical sector is relatively shielded from normal business pressures is of course a huge over-simplification and does not take into account the many challenges that pharmaceutical manufacturers continue to face. The speed of the development of the Covid-19 vaccines has been hugely impressive, but the fact remains that for the vast majority of new drugs, the path from formulation to regulatory approval is usually long and arduous. On average, it can take around ten years for a new medicine to complete the journey from initial discovery to the marketplace, with clinical trials alone taking six to seven years.

The costs are eye-watering as well. A study last year estimated that the median cost of getting a new drug into the market was $985 million, and the average cost was $1.3 billion, although this was much lower compared to previous studies, which have placed the average cost of drug development at $2.8 billion.[1]

Nor is success guaranteed. Indeed, an article in Scientific Reports in 2019 reported an overall failure rate in drug development of over 96%, including a 90% failure rate during clinical development.

I realise that much of the above is preaching to the converted here, but for equipment manufacturers supplying the pharmaceutical industry, it is vital to be aware of the pressures and challenges that the sector has to face, as it is through these that we can best develop the most appropriate solutions to support our customers.

One thing that has become clear in our own dealings with pharmaceutical companies is that they are just as susceptible to commercial pressures as any other industry. Although, even with the huge development costs involved, the rewards for finding the next 'breakthrough' drug can be immense, there is nevertheless still only a small window of opportunity for pharma businesses to recoup their investment before competitive products and generic alternatives start to come onto the market.

At the same time, the commercial environment is becoming tougher, with consumers now more aware and demanding, seeking improved treatments and therapies but at lower or more affordable prices. Healthcare payers are also imposing greater cost constraints on healthcare providers and scrutinising more carefully the value offered by each medicine.

Such pressures mean that pharmaceutical manufacturers need to be as agile and flexible as possible, able to respond quickly to changing customer demands and market requirements.

This is particularly important to meet an emerging trend in the sector for personalised medicines, which are customised to the precise requirements of individual patients. This is creating an increasing need for the production of smaller batches of medications which has in turn led to the introduction of modular manufacturing that allows pharmaceutical processing companies to produce multiple batches of different drugs from the same facility.

The need for greater flexibility has also led companies to streamline their production processes from start to finish, for example moving from batch-to-batch production to continuous manufacturing. The more dynamic nature of this process allows pharmaceutical producers to introduce changes with greater ease and efficiency and can help to avoid excessive downtime.

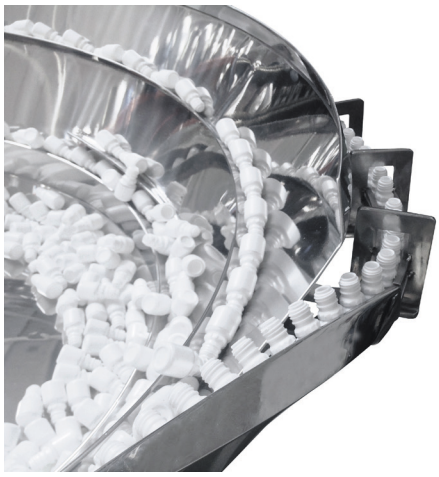
This in turn is leading to greater integration throughout the packing line in order to help increase efficiencies and throughput. The ability of machines to be linked and able to feed information from one to the other helps to ensure that the performance of each piece of equipment can be optimised. For example, container or tube unscramblers can control and regulate the supply of containers to the filling system, and this can then ensure a consistent feed into the capping machine. In this way, speeds can be maximised, and any bottlenecks avoided for a smooth and continuous filling and packing operation.

Another of the benefits of automating the packing line as much as possible is that it allows shopfloor personnel to be deployed to other parts of the operation where they may be more needed. However, the reduction of people on the line, who can intervene quickly in the event of any problem, means it is all the more essential that the equipment continues to function reliably and consistently. Remote monitoring systems can play an important role here.

Such systems allow individual machines, as well as complete single and multiple packing lines, to be monitored by both the equipment supplier and the pharmaceutical manufacturer and packer. This provides a high level of preventative maintenance where potential issues can be identified and even anticipated, so that action can be taken before machines and packing lines suffer any significant downtime.

This also helps to avoid the need for unscheduled engineer call outs, something which will have been of particular benefit during the current pandemic. Equally important, remote monitoring enables service visits to be planned in line with machine usage rather than to a fixed schedule.

In addition, the data capture and analytical abilities of these remote monitoring systems are able to help



pharmaceutical companies manage their operations more profitably. Businesses need to know exactly how much it costs to get a product or pack out of the factory and be able to easily identify areas where there are opportunities for improvement.

Capturing data allows companies to monitor remotely rather than deploying staff simply to monitor the systems. And the information gathered gives businesses the competitive advantage of being able to optimise production and work as efficiently as possible.

Just as the integration of equipment streamlines processes in order to deliver greater efficiencies, the capture of data from multiple areas of the production line enables the building of a more complete picture. This allows companies to be proactive rather than reactive when it comes to improving practices or methods, by using comprehensive reporting to give them the breadth of information to make informed decisions.

The phrase 'To err is human, to forgive divine' is a well-known phrase and a very worthy sentiment but in the high-risk area of pharmaceutical production, where the effects of human error can be catastrophic, any mistakes can be ill afforded. For automated systems, therefore, ensuring the correct set-up procedures are implemented is critical. Here, intuitive touch screens can provide step-by-step instructions and prompts, and these can also incorporate different levels of authorisation access for individual employees.

Increased integration and the availability of real-time reporting and data are key parts of the digital transformation of manufacturing that is being achieved through Industry 4.0 and the emergence of the smart factory. Among its many benefits, the adoption of Industry 4.0 principles will further help pharmaceutical manufacturers to increase productivity and quality and minimise risk.

The pharmaceutical industry is of course heavily regulated, and it is essential that all equipment is manufactured in line with the relevant requirements of each product or application, with accreditations such as FDA, CGMP, CE, UK, and Ex. It is also important for equipment manufacturers to keep abreast of changes to regulations as well as how requirements can vary from country to country.

Packing operations will usually take place in cleanroom or high care environments and the design of equipment needs to reflect this, for example machines that are easy to clean with no dust or dirt traps.

Many complex APIs and formulations may require specialist handling such as Aseptic Manufacturing and Sterile Fill Finish. Aseptic Manufacturing is a process where a drug or medicine and its container and closure are first subjected to separate sterilisation and then brought together. Because there is no process to sterilise the product in its final container, it is vitally important that the container is filled and sealed in the extremely controlled environment of Sterile Fill Finish

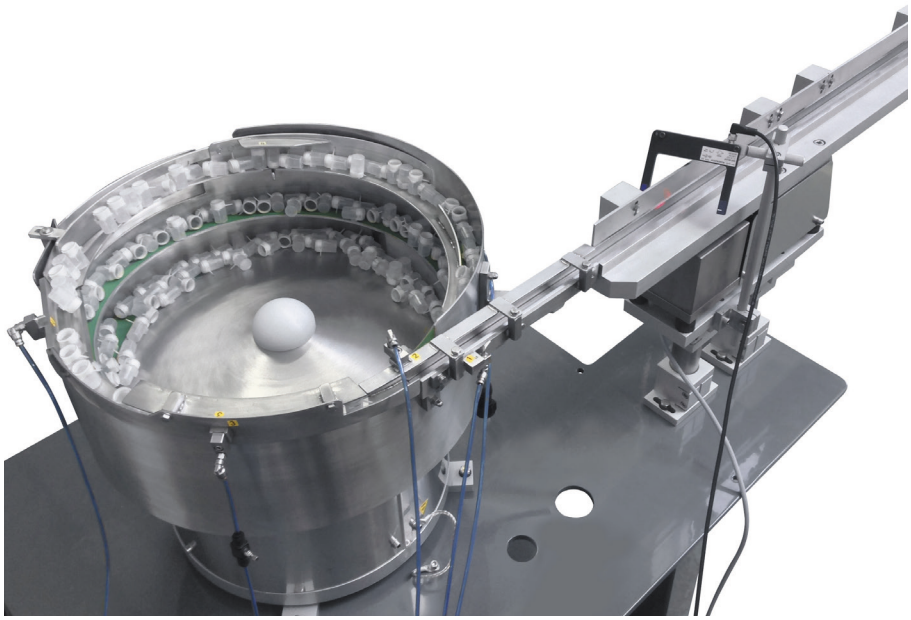
As part of the regulatory process, there is also the need to be able to track a product throughout the supply chain and also trace it back to its original manufacture. Indeed, the national regulations on the serialisation of drugs are perhaps the most important criteria in the global marketing of pharmaceuticals and other pharmaceutical solutions, requiring up-to-date knowledge and understanding of the various obligations from country to country.

To deliver these requirements, serialisation machines are able to print the packs with the relevant information which, depending on individual guidelines, can be machine readable matrix codes or alphanumeric character strings. More advanced systems are also able to provide additional benefits beyond simply printing and verifying codes. For example, they can also weigh the pharmaceutical product on the same installation surface and thus carry out a completeness check. In addition, each individual pack can have tamper-evidence incorporated.

Another enhancement that some systems offer is the ability to perform aggregation, which is the documented combination of product packages into larger packs, from bundles and shipping boxes to cases and pallets. This ensures complete serialisation at every level.

Such track and trace systems and serialisation solutions are also examples of Industry 4.0 in action.

There are other regulations that pharmaceutical packaging is subject to, notably that it provides suitable protection for the drugs or medicines, in particular ensuring that they cannot be unintentionally accessed, especially by children. Such requirements have to be balanced with the need for the pack to be easy enough to open, especially for seniors or those who are less dextrous.



For caps and closures therefore, the challenge is to ensure that the closure is affixed and tightened correctly during the filling and packing process so that containers can be transported safely throughout the supply chain, without making them too difficult for the end-user to open.

Latest capping technology can play an important role here, using fully programmable torque, speed, applied force and vertical positioning of the capping head to ensure more precise placement and turning. The new systems also offer greater flexibility in terms of the types of closures that they can handle compared to capping machines that rely on mechanical cams and clutches and which are more limited.

One of the implications of all the regulatory frameworks that pharmaceutical products must adhere to and the high care manufacturing process that these often involve is that pharmaceutical products require some of the most expensive production areas in the world. As a result, space is usually at a premium. For equipment manufacturers, therefore, the focus in our new machinery development process is to minimise the footprint of each new model, with the aim of achieving increased functionality, speed and efficiency in the smallest possible space.

The pharmaceutical industry has to deal with many of the same commercial pressures as other industries, and in many cases the nature of the products mean companies are subjected to much greater control and regulation. For the filling and packing process, the need to maximise efficiencies and productivity, to be agile and flexible and able to respond quickly to customer demands are all the more essential. Selection of the most appropriate equipment is key to achieving the Right First Time approach that will help companies to meet customer requirements and make the most of all opportunities.

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